

## REMARKS

Applicants responded to the Office Action mailed December 16, 2002, on June 16, 2003. In reply to Applicants' response, the PTO issued a Notice of Non-Compliant Amendment (Voluntary Revised Practice). The content of this amendment corresponds to that of the amendment filed June 16, 2003, except for a minor change made to provide proper antecedent basis to claims 229 and 235. Further, this amendment is compliant with the Voluntary Revised Practice. Applicants respectfully request entry of this amendment and consideration of the remarks presented herein.

Applicants would like to thank Examiner Ketter for taking the time to discuss the Notice of Non-Compliant Amendment with Applicants' representative on July 23, 2003. As agreed during that conversation, Applicants hereby re-submit the response to the Office Action mailed on December 16, 2002. Applicants submit that this response has a complete listing of all the claims (canceled claims 1-217 and new claims 218-268). Further, it includes the text of all claims that will be under examination after entry of the amendment (claims 218-268). In addition, Applicants submit that the claims have been presented in ascending numerical order (1 to 268). Accordingly, Applicants submit that this amendment is compliant with the Voluntary Revised Practice and request entry of this amendment.

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 were pending in the instant Application. Claims 5-9, 11, 12, 18-27, 29, 30, 32, 33, 36, 38-71, 73, 75, 77-82 and 85-217 were canceled in the preliminary amendment filed on June 5, 2001. With the instant amendment, Applicants have canceled claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84, without prejudice, and added new claims 218-268. After entry of this amendment, original claims 1-217 would be canceled and new claims 218-268 would be pending.

Applicants expressly reserve the right to pursue any canceled subject matter in one or more related, continuation, divisional or continuation-in-part application(s).

Support for new Claims 218-268 can be found in the specification at, *inter alia*, pages 27-34, 69-72, 248-268 and Claims 165-217 as originally filed. As the claims are fully supported by the specification and claims as originally filed, they do not constitute new matter. Applicants hereby request entry of the claims into the record. Applicants submit that claims 218-268 satisfy all the criteria for patentability and are in condition for allowance. An early indication of the same and passage of claims 218-268 to issuance is therefore kindly solicited.

**I. THE REJECTIONS UNDER THE DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING SHOULD BE WITHDRAWN**

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74 and 83 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-3, 13-17, 30, 37, 38, 40, 45, 70 and 71 of U.S. Patent No. 5,837,464. Further, Claims 1, 14, 28, 34, 35, 37, 72, 74, 83 and 84 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1, 2, 6, 7, 8, 10, 24, and 26 of U.S. Patent No. 5,837,464. At the outset, as pointed out, above, none of Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 is currently pending. However, to the extent the Examiner contends one or both of these rejections would apply to the newly added claims, Applicants assert that the pending claims are patentably distinct from those of U.S. Patent No. 5,837,464.

**II. THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH (ENABLEMENT), SHOULD BE WITHDRAWN**

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly being not enabled. As pointed out, above, none of Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 is currently pending. However, for the reasons set forth below, Applicants assert that the pending claims are fully enabled under 35 U.S.C. §112, first paragraph.

The PTO bases its rejection of Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 on the contention that they do not recite a functional connection between the patient-derived segment and the indicator gene. (Office Action, p. 3).

New Claims 218-268 are fully enabled by the specification as originally filed and merely clarify that which Applicants have always considered the claimed subject matter. In particular, in the methods recited in each of the claims there is explicitly pointed out the functional connection between the patient-derived segment and the indicator gene: the indicator gene expression is dependent upon the patient-derived segment. As such, the above-summarized concern with respect to Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 is not relevant to the enablement of the subject matter recited in the pending claims.

### **III. THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH (WRITTEN DESCRIPTION), SHOULD BE WITHDRAWN**

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 have been rejected as allegedly containing subject matter which is not described in the specification sufficiently to convey to one skilled in the art that the inventors had possession of the full scope of the claimed invention at the time of filing the application. As pointed out, above, none of Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 is currently pending. However, for the reasons set forth below, Applicants assert that the subject matter of the pending claims is described in the specification sufficiently to convey to one skilled in the art that the inventors had possession of the full scope of the claimed invention at the time of filing the application.

The PTO bases its rejection of Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 on the contention that “[t]he genus of viruses encompassed by the instant claims is vast, including at least all pathogenic viruses.” (Office Action, p. 4).

The subject matter of new Claims 218-268 is described in the specification sufficiently to convey to one skilled in the art that the inventors had possession of the full scope of the claimed invention at the time of filing the application. In particular, new Claims 218-235 and 249-268 are directed to subject matters relating to Human Cytomegalovirus (HCMV) and new Claims 236-248 are directed to subject matters relating to betaherpesvirinae, of which HCMV is an important member. The subject matter of new Claims 218-268 can be found in the specification at, *inter alia*, pages 27-34, 69-72, 248-268 and Claims 165-217 as originally filed. As such, the above-summarized concern with respect to Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 is not relevant to the description in the specification of the subject matter recited in the pending claims.

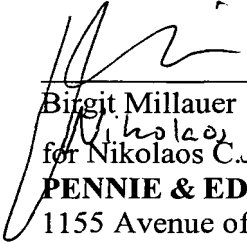
### **CONCLUSION**

In light of the above amendments and remarks, Applicants respectfully submit that Claims 218-268 satisfy all the criteria for patentability and are in condition for allowance. Applicants request that the Examiner reconsider this application with a view towards allowance and solicit an early passage of Claims 218-268 to issuance. The Examiner is invited to call the undersigned attorney, if a telephone call could help resolve any remaining items.

No fee is believed due with this Amendment. A three-month extension of time was sought for the response filed on June 16, 2003. As this response to the Notice of Non-Compliant Amendment is being filed on August 4, 2003, the Monday following August 3, 2003, deadline, Applicants submit that this response is timely filed. However, pursuant to 37 CFR § 1.136(a)(3), the Commissioner is hereby authorized to charge all required fees, including fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Pennie & Edmonds, LLP U.S. Deposit Account No. 16-1150 (order no. 11068-051-999).

Respectfully submitted,

Date: August 4, 2003

  
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